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**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
097310,844	05/12/99	ECKER	D IBIS-0171

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EXAMINER
SHIBUYA, M

ART UNIT	PAPER NUMBER
1635	19

DATE MAILED: 10/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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File

Office Action Summary

Application No.

09/310,844

Applicant(s)

ECKER ET AL.

Examiner

MARK SHIBUYA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 28, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-113 is/are pending in the application.
- 4a) Of the above, claim(s) 1-86, 101-107, and 109 is/are withdrawn from consideration.
- 5) ☐ Claim(s) is/are allowed.
- 6) ☒ Claim(s) 87-100, 108, and 110-113 is/are rejected.
- 7) ☐ Claim(s) is/are objected to.
- 8) ☐ Claims are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. .
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). .
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4-8 20) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group VII, claims 87-100, 108 and 110-113 in Paper No. 15, filed 5/24/01, is acknowledged. The traversal is on the ground(s) that (1) simply because "[t]he RNA molecules have different molecular structures and nucleotide sequences does not mean that they have 'different modes of operation, different functions or different effects.' Indeed the RNA molecules recited in the claims of Groups I, III, V and VII are all portions of interleukin-2. . . . Because the RNA molecules recited in the claims of Groups I, III, V and VII are derived from the same biomolecule and are used by Applicants for the same purposes, the RNA molecules are clearly related."

a. This is not found persuasive because applicant's assertion that the RNA molecules recited in the claims of Groups I, III, V and VII are all portions of interleukin-2 is not true. For example, elected independent base claim 87, which is drawn to an RNA molecule comprising a defined secondary structure, recites:

87. An RNA comprising a joined sequence of at least twenty-nine but not more than seventy nucleotides and having secondary structure defined by: five nucleotides forming a first side of a first double stranded region; four nucleotides forming a first side of a first end loop region; five nucleotides forming a second side of said first double stranded region; two nucleotides forming a bulge between said first double stranded region and a second double stranded region; five nucleotides forming a first side of a second double stranded region; three nucleotides forming a second end loop region; and five nucleotides forming a second side of said second double stranded region.

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Claim 87 of the instant application. Claim 87 cannot recite a portion of interleukin-2 because claim 87 does not recite any particular nucleotide sequence, and certainly not the nucleotide sequence of interleukin-2. The claimed RNA molecule of Claim 87 is instead defined by *comprising* a secondary structure of loops and double-stranded regions. These loops and double-stranded regions result from intra-strand complementarity; however, this complementarity may result from either G-C or A-U base pairs, and so that nucleotide sequences, other than that of interleukin-2, are encompassed by this claim. In other words, the RNA of claim 87 embraces RNA molecules in addition to interleukin-2. For example, SEQ ID NO: 24 (uaugauucuuuuuguaagcccuaggggcu) of *elected* claim 111, encoding a portion of human interleukin-2, is encompassed by SEQ ID NO: 23, (nnngauncuuunnguaagcccnangngnn), of *elected* claim 110, comprising nucleotide "n", which can be any nucleotide (e.g., A, T, G, C, U).

Furthermore, comparison to independent base claim 1, reveals by observation that the claimed invention is based upon differences in RNA secondary structure. Claim 1 recites:

1. An RNA comprising a joined sequence of at least sixty-two but not more than seventy nucleotides and having secondary structure defined by: five nucleotides forming a first side of a first double stranded region; four nucleotides forming a first side of a first end loop region; five nucleotides forming a second side of said first double stranded region; three nucleotides forming a first side of a first internal loop region; five nucleotides forming a first side of a second double stranded region; one nucleotide forming a first side of a second internal loop region; six nucleotides forming a first side of a third double stranded region; eight nucleotides forming a second end loop region; six nucleotides forming a second side of said third double stranded region; one nucleotide forming a second side of said second internal loop region; five nucleotides forming a second side of said second double stranded region; two nucleotides forming a second side of said first internal loop region; three nucleotides forming a first side of a fourth double stranded region; five nucleotides forming a third end loop region; and three nucleotides forming a second side of said fourth double stranded region.

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Claim 1 of the instant application. Because the claimed inventions are drawn to loops and double-stranded regions, and because claims 1 and 87 recite RNA molecules with secondary structures with differing arrangements of loops and double-stranded regions, the examiner does not find the inventions of nonelected claim 1 and elected claim 87 to be the same invention. In dependent claims, applicant recites the RNA of claims 1 or 87, wherein said RNA comprises a portion of interleukin-2 RNA whose description matches the claimed secondary structure; and the specification contemplates interleukin-2 RNA as a preferred embodiment. But the inventions of claim 1 and 87, for example, are not RNA of particular genes, *i.e.*, particular nucleotide sequences, but rather secondary structures whose parameters may be met by RNA nucleotide sequences other than interleukin-2 RNA, and whose secondary structures themselves, differ from one another. The examiner does not find that the search for the RNA secondary structure recited in claim 87 would necessarily be required of a search of the independent and distinct RNA secondary structures claimed in inventions of Group I or the other Groups. Because the secondary structure is the *very* thing claimed, restriction for examination purposes based upon differing secondary structures is proper.

b. Applicant has not distinctly and specifically point out the supposed errors in the restriction requirement in regards to the inventions of Groups I, III, V and VII, (claims 1-20, 31, 33-48, 56, 58-73, 81, 83-100, 108, 110-113), drawn to RNA versus the inventions of Groups II, IV, VI and VIII, (claims 21-30, 32, 49-55, 57, 74-80, 82, 101-107, and 109), drawn to RNA *in*

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silico, so that the election has been treated as an election without traverse in regards to the Groups II, IV, VI and VIII, drawn to RNA *in silico*, (MPEP § 818.03(a)).

c. Applicant notes as a preliminary matter, that the restricted claims of Group VIII, as set forth in the restriction requirement, was duplicative of Group VI (claims 74-80 and 82) and should have instead recited claims 101-107 and 109. The examiner agrees, gratefully thanks the applicant for clarifying the record, and sincerely regrets any inconvenience that may have resulted to the applicant.

2. The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1-86, 101-107, and 109, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 15, filed 5/24/01.

Information Disclosure Statement

4. The information disclosure statement (IDS) of Paper No. 7, filed 6/14/00, fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The IDS of Paper No. 7, filed 6/14/00, has been placed in the application file, but the information referred to therein for applicant's references FU, FV, VW, FX, FY, FZ, GA, GB, GC, GD, GE, GF, GG and GH of the IDS of Paper No. 7, filed 6/14/00, have not been considered.

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5. The following U.S. Application Serial Numbers have been considered: 09/076,405, Reference GP, IDS filed 5/12/1998; 09/076,440, Reference GQ, IDS filed 5/12/1998; 09/076,447, Reference GR, IDS filed 5/12/1998. The following U.S. Application Serial Numbers are unavailable to the examiner, have not been considered, and will be considered as they do become available: 09/076,206, Reference GM, IDS filed 5/12/1998; 09/076,214, Reference GN, IDS filed 5/12/1998; 09/076,404, Reference GO, IDS filed 5/12/1998. The citations to the U.S. Application Serial Numbers on the PTO-1449 have been removed as failing to comply with 37 CFR 1.98, because citations must have publication dates pursuant to 37 CFR 1.98, but U.S. Applications, (unlike U.S. Patents), do not have publication dates.

Specification

6. The specification is objected to because the instant specification variously and frequently recites embedded hyperlinks and/or other forms of browser-executable code, that are impermissible and must be deleted. The attempt to incorporate subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01(p), paragraph I regarding incorporation by reference. Furthermore if the application should issue and be placed on the Office web page, the URL may be interpreted as a valid HTML code and become a live web link, transferring an user to a commercial web site. Office policy does not permit the Office to link to any commercial site because the Office exercises no control over the organization, views or accuracy of the information contained on these outside sites.

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Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 87-93 and 108 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 87-93 and 108, drawn to “[a]n RNA”, reads upon naturally occurring biological nucleic acids that are RNA, which are products of nature that do not clearly show the “hand of man”. Language at the beginning of this claim such as “A purified and isolated RNA” would remove the instant rejection.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 87-93 and 94-100 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 87 and 94, and their dependent claims, recite the limitations “a second double stranded region” in line 8 and “said second double stranded region” in line 10. There is indefinite antecedent bases for these limitations in the claims. It is unclear whether “a second

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double stranded region” in line 8 and “said second double stranded region” in line 10, is referring to “a second double stranded region;” in lines 6-7.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

12. Claims 87-100, 108, 110, 112, and 113 are rejected under 35 U.S.C. 102(b) as being anticipated by McKnight et al., Immunogenetics 30, 145-147 (1989).

a. Claims 87-100, 108, 110, 112, and 113 are drawn to RNA comprising a joined sequence of at least twenty-nine but not more than seventy nucleotides and having secondary structure defined by: five nucleotides forming a first side of a first double stranded region; four nucleotides forming a first side of a first end loop region; five nucleotides forming a second side of said first double stranded region; two nucleotides forming a bulge between said first double stranded region and a second double stranded region; five nucleotides forming a first side of a second double stranded region; three nucleotides forming a second end loop region; and five

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nucleotides forming a second side of said second double stranded region; wherein said RNA comprises the sequences of SEQ ID NOs: 23 or 25.

b. McKnight et al., *Immunogenetics* 30, 145-147 (1989), throughout the publication and especially at Figure 1, nucleotides 612 to 640, teach cDNA encoding the rat interleukin-2 gene, which absent evidence to the contrary, encode RNA comprising the sequence of SEQ ID NOs: 23 and 25 and having a joined sequence of at least twenty-nine but not more than seventy nucleotides and, absent evidence to the contrary, having secondary structure defined by: five nucleotides forming a first side of a first double stranded region; four nucleotides forming a first side of a first end loop region; five nucleotides forming a second side of said first double stranded region; two nucleotides forming a bulge between said first double stranded region and a second double stranded region; five nucleotides forming a first side of a second double stranded region; three nucleotides forming a second end loop region; and five nucleotides forming a second side of said second double stranded region.

13. Claims 87-100, 108, and 110 and 111 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al., *Proc. Natl. Acad. Sci. USA*, Vol. 82, pp. 7284-7288 (November 1995).

a. Claims 87-100, 108, and 110 and 111 are drawn to RNA comprising a joined sequence of at least twenty-nine but not more than seventy nucleotides and having secondary structure defined by: five nucleotides forming a first side of a first double stranded region; four nucleotides forming a first side of a first end loop region; five nucleotides forming a second side of said first

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double stranded region; two nucleotides forming a bulge between said first double stranded region and a second double stranded region; five nucleotides forming a first side of a second double stranded region; three nucleotides forming a second end loop region; and five nucleotides forming a second side of said second double stranded region; wherein said RNA comprises the sequences of SEQ ID NOs: 24.

b. Chen et al., *Proc. Natl. Acad. Sci. USA*, Vol. 82, pp. 7284-7288 (November 1995), throughout the publication and especially at p. 7286, Figure 3, nucleotides about 650-680, teach cDNA encoding the gibbon and human interleukin-2 gene, which absent evidence to the contrary, encode RNA comprising the sequence of SEQ ID NO: 24 and having a joined sequence of at least twenty-nine but not more than seventy nucleotides and, absent evidence to the contrary, having secondary structure defined by: five nucleotides forming a first side of a first double stranded region; four nucleotides forming a first side of a first end loop region; five nucleotides forming a second side of said first double stranded region; two nucleotides forming a bulge between said first double stranded region and a second double stranded region; five nucleotides forming a first side of a second double stranded region; three nucleotides forming a second end loop region; and five nucleotides forming a second side of said second double stranded region.

14. Claims 87-91, 94-98, 108, 110, 112, and 113 are rejected under 35 U.S.C. 102(e) as being anticipated by anticipated by Fu et al., Patent No. 6,090,620.

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a. Claims 87-91, 94-98, 108, 110, 112, and 113 are drawn to RNA comprising a joined sequence of at least twenty-nine but not more than seventy nucleotides and having secondary structure defined by: five nucleotides forming a first side of a first double stranded region; four nucleotides forming a first side of a first end loop region; five nucleotides forming a second side of said first double stranded region; two nucleotides forming a bulge between said first double stranded region and a second double stranded region; five nucleotides forming a first side of a second double stranded region; three nucleotides forming a second end loop region; and five nucleotides forming a second side of said second double stranded region; wherein said RNA comprises the sequences of SEQ ID NOs: 23 or 25.

b. Fu et al., Patent No. 6,090,620, throughout the patent and especially at col. 2, lines 13-36, col. 5, lines 8-24, col. 6, line 21-col. 7, line 2, col. 11, lines 31-47, col. 19, lines 9-14, col. 43, lines 49-67 and nucleotides 26015 to 26041 of SEQ ID NO: 209, teach DNA encoding the WRN gene, which absent evidence to the contrary, encode RNA comprising the sequence of SEQ ID NOs: 23 and 25 and having a joined sequence of at least twenty-nine but not more than seventy nucleotides and, absent evidence to the contrary, having secondary structure defined by: five nucleotides forming a first side of a first double stranded region; four nucleotides forming a first side of a first end loop region; five nucleotides forming a second side of said first double stranded region; two nucleotides forming a bulge between said first double stranded region and a second double stranded region; five nucleotides forming a first side of a second double stranded region;

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three nucleotides forming a second end loop region; and five nucleotides forming a second side of said second double stranded region.

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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mark L. Shibuya (SRC)*, whose telephone number is (703) 308-9355, and/or to the patent analyst, *Katrina Turner*, whose telephone number is (703) 305-3413.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader* may be reached at (703) 308-0447.

17. Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is (703) 308-0196.

Mark L. Shibuya
Patent Examiner
Technology Center 1600
October 25, 2001



SEAN MCGARRY
PRIMARY EXAMINER